

Exhibit B

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Re: United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., et al., No. 05-11084-PBS

Dear Ms. Reid,

On November 30, 2009, plaintiffs' expert Dr. Mark Duggan submitted a letter that included "another look at ... issues" and several "technical corrections". These issues and errors with Dr. Duggan's initial report filed on January 23, 2009 were identified in my initial report filed on March 6, 2009. Dr. Duggan's letter was accompanied by supporting tables, new programming scripts, logs and other supporting materials totaling 123 individual electronic files. In this letter I comment on Dr. Duggan's new analyses and related issues.¹ I reserve the right to update my analysis if additional information becomes available. In addition, I reserve the right to supplement or modify my opinions, if warranted, and to prepare additional supporting materials, such as summaries, graphical exhibits, or charts.

A. "Technical correction" to Medicare damages on albuterol sulfate

In his initial report, Dr. Duggan had calculated albuterol sulfate Medicare damages of \$2.25 million on a paid amount of \$1.3 billion. This represented a damage percentage of 0.17%. In my initial report, I identified several errors with Dr. Duggan's calculations. Dr. Duggan has now acknowledged these errors and reports a lower damage estimate of \$0.3 million. Hence his corrected damages percentage is 0.02%.

B. Correction to Dey and Roxane scenarios for ipratropium bromide

Dr. Duggan also presents corrected calculations for the scenarios where he calculates ipratropium bromide damages for Dey and Roxane jointly. He presents two different joint scenarios: Dey/Roxane and Dey/Roxane plus NovaPlus.² As discussed in my initial report, these joint scenarios are not logically consistent with plaintiffs' theory of the case. Moreover, these joint scenarios are an arbitrary and unreliable basis for calculating damages. As I demonstrate in this letter, both the total magnitude and the attribution of damages in plaintiffs' joint scenarios are entirely dependent on plaintiffs' arbitrary

¹ In addition to Dr. Duggan's November 30, 2009 letter I have also reviewed depositions of DMERC employees Carolyn Helton dated October 16, 2009 and Robin Stone dated October 14, 2009.

² The two different joint scenarios considered by Dr. Duggan differ in his treatment of a particular set of three Roxane ipratropium bromide NDCs marketed as NovaPlus. In the Dey/Roxane plus NovaPlus scenario, Dr. Duggan replaces the actual AWP's found in the array with his calculated 'but-for' AWP for each Dey and Roxane NDCs including NovaPlus NDCs. However in the Dey/Roxane scenario, Dr. Duggan does not replace AWP's for NovaPlus NDCs. Since NovaPlus NDCs were treated as brand drugs by three of the DMERCs, Dr. Duggan has not provided any rationale for his Dey/Roxane joint scenario where he does not replace AWP's for NovaPlus. All discussion here could apply to both joint scenarios.

assumptions. Dr. Duggan has not presented any coherent theory of liability or evidence to support these joint scenarios.

Although I disagree with the entire premise behind Dr. Duggan's damage calculations, his Dey-only scenario damage calculations nevertheless illustrate an important point. For much of the time period at issue, Medicare reimbursement levels for ipratropium bromide could not have been affected had Dey published a lower AWP. This is because Medicare reimbursements for ipratropium bromide were generally based on the median AWP calculated from an array of NDCs.³ In contrast to an average calculation, a median price may not be at all affected by changes to a subset of prices included in its calculation. Figure A visually presents the DMERC-quarters where Dr. Duggan calculated Dey damages in the Dey-only scenario. Starting in 2001, Dr. Duggan calculates no damages for Dey because lowering the AWP for Dey's NDCs (to his but-for AWP) would not have moved the median at all. The primary reason for this is that, as shown in Figure B, other manufacturers and NDCs appeared in the market in 2001 and their AWP's were included in the DMERC arrays. As a result, the AWP's for Dey's three ipratropium bromide NDCs ceased to have any direct effect on the median calculation used by Medicare for its reimbursements.

What therefore stands out about Dr. Duggan's joint Dey/Roxane damage scenarios is that the bulk of the damages calculated for Dey in those scenarios stem from precisely the same time period during which Dr. Duggan's own calculations indicate that Dey's AWP no longer could have had any impact on Medicare reimbursement. This is also illustrated in Figure B. In essence, the joint damage scenarios make Dey's damages contingent on the assumptions one might make about the actions of other manufacturers. However, neither the complaint in this case, nor Dr. Duggan's expert report or subsequent disclosures, articulate a theory by which Dey should be held liable for damages during a period when it could not have unilaterally affected the amount that Medicare paid for ipratropium bromide.

The choice of a Dey/Roxane joint scenario is also arbitrary. For much of the time period for which joint damages are calculated, the DMERCs' arrays also included AWP's for several other manufacturers' NDCs of ipratropium bromide. However, no analysis has been presented by Plaintiffs to suggest that the pricing policies of Dey and Roxane were unique. Indeed, applying Dr. Duggan's damage methodology to other sets of manufacturers in a joint fashion appears to generate large and overlapping numbers that Dr. Duggan would identify as damages.

Examination of an actual DMERC array illustrates this point. Figure C attached to this letter shows an example DMERC array that was used by AdminaStar in the second quarter of 2002. As shown in Figure C, AdminaStar included 13 NDCs from five different manufacturers in its array to arrive at an actual median of \$3.52 as shown in the third column. Replacing Dey's AWP's in this particular array with Dr. Duggan's but-for AWP's for Dey's NDCs has no effect on the median, and as a result he calculates no damage for this period in the Dey-only scenario. However, Dr. Duggan's joint Dey/Roxane scenario damage calculation, which replaces both Dey and Roxane's AWP's

³ These arrays were constructed on a quarterly basis by each regional DMERC.

with his but-for AWP, results in a lower median of \$1.80.⁴ The aggregate damage per unit for AdminaStar in Q2 2002 under that scenario would thus be \$1.72 (\$3.52-\$1.80). However, if one chose to apply Dr. Duggan's joint damage methodology to an alternative set of manufacturers appearing in the array – for example all generic manufacturers other than Dey and Roxane – the resulting but-for median would be even lower at \$1.22.⁵ In this instance, the aggregate damage per unit calculated under Dr. Duggan's methodology for this DMERC in Q2 2002 would be \$2.30 (\$3.52-\$1.22) which is actually larger than the damage calculated under the joint Dey/Roxane scenario. Moreover, although alternative set of manufacturers do not overlap with Dr. Duggan's joint scenario, the damages calculated under Dr. Duggan's methodology must be overlapping because “damages” from the two scenarios sum to more than the total amount that Medicare paid ($\$1.72 + \$2.30 = \$4.02$). This implies that the Dey/Roxane joint scenario would almost certainly involve double counting of “damages” that might have nothing to do with either manufacturer.⁶

This example illustrates the arbitrary nature of the Plaintiffs' joint damage scenarios. Virtually any damage number could be generated by simply manipulating which manufacturers to include or exclude. In effect, the joint scenario assumes causation and liability for the defendant manufacturers without providing any theory or evidence in support of that choice. Setting aside the lack of theoretical foundation presented for the joint scenario, the obvious risk of double-counting involved in this type of exercise raises serious reliability concerns.

The only damages scenario presented by Dr. Duggan that is consistent with the plaintiffs' allegation involving Dey's published prices is the Dey-only scenario. However, as I discussed in my initial report, Dey's published prices and actual transaction prices were well known to the reimbursing authorities like the state Medicaid agencies and the CMS. Additionally, Dey consistently lowered its WAC to reflect its falling transaction prices. Dey also submitted its AMPs to CMS on a quarterly basis that showed actual prices received by Dey. Finally, the Medicaid and Medicare reimbursements were the result of active and knowledgeable policy choices. Thus in my opinion, there is no liability and damages resulting from reimbursements based on Dey's published prices.

C. Dr. Duggan's damages allocation methodology

Dr. Duggan relies on Medicaid market shares to allocate damages calculated in his joint scenarios without any support and Dr. Duggan's use of Medicaid market shares are

⁴ Source: Duggan damage calculations updated 11/30/2009.

⁵ In order to calculate ‘but-for’ AWP I used wholesaler data which has been produced in this matter and followed Dr. Duggan's methodology. As I have discussed in detail in my reports, there is no support for Dr. Duggan's ‘but-for’ AWP calculations in the generic industry. Since I also find that wholesaler transaction prices across manufacturers and NDCs appear comparable, I substituted the overall average prices where particular NDCs do not appear in the wholesaler data. I note also that a brief examination of wholesaler data from this period suggests that there is likely little to distinguish the transactional pricing of defendants from non-defendants.

⁶Dr. Duggan's joint scenarios essentially assume that all other manufacturers' AWP are appropriate but the similar and in many instances even lower AWP for Dey and Roxane are not. Plaintiffs have not produced analysis that examines the published AWP of all other NDCs in the array.